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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,950	03/30/2004	Joel S. Douglas	032994-113	8266
21839	7590	11/30/2004	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			KENNEDY, SHARON E	
POST OFFICE BOX 1404			ART UNIT	PAPER NUMBER
ALEXANDRIA, VA 22313-1404			3762	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/814,950	DOUGLAS, JOEL S.
	Examiner Sharon Kennedy	Art Unit 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on \_\_\_\_\_.
- 2a)  This action is FINAL.                            2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 1-17 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1 and 3-17 is/are rejected.
- 7)  Claim(s) 2 is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some \* c)  None of:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 03302004

- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_.

## **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

### ***Claim Objections***

Claim 17 is objected to because of the following informalities: In line 1 of claim 17, "the" is misspelled as "he". Appropriate correction is required.

Claim 3 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 2. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). (Claims 2 and 3 appear to be the same claim.)

### ***Claim Rejections - 35 USC § 112***

Claims 8-12, 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 8, 11, 12 and 14 recite "the connecting hub", however, this limitation has not been previously recited.

***Claim Rejections - 35 USC § 102***

Claims 1, 4, 5, 7-14, 16 and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Konopka et al., US 4,755,173. See especially figures 8 and 9, wherein the infusion needle is aligned on a separate axis from the cannula.

Claims 1, 4-7, 12-14, 16 and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Marggi, US 6,203,866. See especially figure 4, wherein the needle 4 is again on a separate axis from the cannula.

***Claim Rejections - 35 USC § 103***

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Konapka et al., '173 in view of Finch, US 5,562,617. Konapka discloses all of the claimed embodiments except for the pre-slit septum. Finch exemplifies that such septums are well known in the art and are an alternate means of sealing a septum. It would be obvious to one of ordinary skill in the art to substitute the needle septum of Konapka for the slit septum of Finch to employ a different type of septum sealing.

***Allowable Subject Matter***

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Claim 2 is allowable because the prior art does not teach or fairly suggest the

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apparatus wherein the infusion cannula and the infusion needle are aligned on separate non-identical axis which are positioned parallel to one another. This has advantages over the prior art as set forth in applicant's paragraph [0005]. The septum will not be pierced in the same place over and over.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571/272-4955.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Sharon Kennedy*  
Sharon Kennedy  
Primary Examiner  
Art Unit 3762

Sek